

510(k) Summary
JAN 28 2009
PILOT® Spinal System

Submitted By: Life Spine
2401 W. Hassell Road, Suite 1535
Hoffman Estates, IL 60169
Telephone: 847-884-6117
Fax: 847-884-6118

510(k) Contact: Rebecca Brooks
Life Spine
2401 W. Hassell Road, Suite 1535
Hoffman Estates, IL 60169
Telephone: 847-884-6117
Fax: 847-884-6118

Date Prepared: December 23, 2008

Trade Name: PILOT® Spinal System

Common Name: Pedicle screw spinal system

Classification: 21 CRF 888.3070
Pedicle Screw Spinal System

Device Product Code: *MNI: Orthosis, Spinal, Pedicle Fixation*
MNH: Orthosis, spondylolisthesis spinal fixation

Device Description:

When implanted in the thoracic, lumbar, and/or sacral spine, the PILOT® Spinal System provides additional support during spinal fusion. The PILOT® Spinal System consists of screws and rods in a variety of shapes and sizes. The PILOT® Spinal System is manufactured from medical grade titanium alloy and will be sold non-sterile. Modifications to the PILOT® Spinal System that are the subject of this submission are confined to the modification of the tightening mechanism of the body component.

Intended Use of the Device:

Internal fixation implants are load-sharing devices intended to stabilize and maintain alignment until normal healing occurs. Implants are not intended to replace normal body structures or bear the weight of the body in the presence of incomplete bone healing.

The PILOT® Spinal System, when properly used, is intended for posterior pedicle screw fixation of the non-cervical posterior spine in skeletally mature patients. It provides stabilization and immobilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities.

When used as a posterior spine thoracic/lumbar system, the PILOT® Spinal System is indicated for one or more of the following: (1) degenerative disc disease (is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), (2) trauma (i.e. fracture or dislocation), (3) curvatures (scoliosis, kyphosis, and/or lordosis), (4) spinal tumor, (5) failed previous fusion (6) pseudarthrosis, (7) spinal stenosis, (8) spondylolisthesis.

Performance Data:

Biomechanical testing in accordance with ASTM F1717 was conducted to demonstrate substantial equivalence.

Substantial Equivalence:

The PILOT® Spinal System was shown to be substantially equivalent to previously cleared devices in indications for use, design, function, and materials used.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Life Spine
% Ms. Rebecca M. Brooks
Project Coordinator
2401 W. Hassell Road
Suite 1535
Hoffman Estates, IL 60169

JAN 28 2009

Re: K083865
Trade/Device Name: PILOT® Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: II
Product Code: MNI, MNH
Dated: December 23, 2008
Received: December 29, 2008

Dear Ms. Brooks:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

Page 2 – Ms. Rebecca M. Brooks.

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) number (if known): K083865

Device Name: **PILOT® Spinal System**

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Prescription Use x
(Part 21 CFR 801 Subpart D)

And/Or

Over-the-Counter Use
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER
PAGE IF NEEDED)


(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

510(k) Number 1L083865